UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Subcategory Docket: 06-CV-11337-PBS
THIS DOCUMENT RELATES TO	)	Judge Patti B. Saris
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al., No. 06-CV-11337-PBS	)	Magistrate Judge Marianne B. Bowler

REPLY STATEMENT OF UNDISPUTED MATERIAL FACTS SUPPORTING ABBOTT LABORATORIES INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT

AND

ABBOTT LABORATORIES INC.'S MOTION *IN LIMINE* TO EXCLUDE CERTAIN OPINIONS PROFFERED BY PLAINTIFFS' EXPERT MARK G. DUGGAN, PH.D.

Dated: August 28, 2009

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PRELIMINARY STATEMENT

In this Reply Statement of Undisputed Material Facts, Abbott submits replies to certain of the United States Responses (Dkt. No. 6320) to Abbott's Statement of Undisputed Material Facts in Support of its Motion for Partial Summary Judgment and to Exclude Certain Opinions of Plaintiffs' Expert (Dkt. No. 6189), where the United States included additional assertions as part of its responses to Abbott's statement of facts, and where Abbott believes a reply would be of assistance to the Court in showing that there is no genuine dispute as to Abbott's original undisputed and material facts. Abbott has not submitted replies for those responses where the United States admitted the facts therein, or for which Abbott believes it is readily apparent that there is no genuine dispute as to the stated facts in Abbott's original Statement of Material Undisputed Facts.

The United States' frequent response that "Abbott has correctly, but selectively, quoted excerpts" of documents and depositions lacks any legal basis, as Abbott is not required to include the entirety of a document or deposition in its Local Rule 56.1 statement. Rather, the Local Rules expressly call for a "concise statement of the material facts" with "page references to affidavits, documents, and other documentation." D. Mass. Local R. 56.1.

In addition, the United States' frequent response that witnesses' testimony was "given in their individual capacities," and not on "behalf of their respective States" or CMS, is immaterial and does not create a genuine dispute of the facts asserted therein. There is no rule that only testimony from 30(b)(6) witnesses is relevant to or admissible in this matter. To the contrary, those witnesses testifying in their individual capacity (*e.g.*, Florida's Jerry Wells, Ohio's Robert Reid, Tennessee's Leo Sullivan, and Minnesota's Cody Wiberg) were typically identified *by the United States* as potential trial witnesses, and in any event were long-time state Medicaid or CMS personnel with actual first-hand knowledge of the facts.

I. CASE BACKGROUND

20. The United States' purported "dispute" over whether the Abbott Home Infusion Partnerships constituted new claims, and its characterization of the nature of its Home Infusion Claims and their status vis-à-vis the relator's complaint and original complaint-in-intervention involve an issue of law for the Court to determine. It does not create a material dispute of fact precluding summary judgment.

II. MEDICAID AND MEDICARE DRUG PAYMENT REGULATIONS AND POLICY

A. Medicaid

21. The United States admits to the substance of this paragraph. The remainder of the United States' response is unresponsive and immaterial.

The United States' claim that the quoted publication is "hearsay" should be disregarded. The United States does not deny that the *Medicaid Pharmacy Bulletin* was "published with input from state Medicaid pharmacy officials," and admits that state officials in this case had copies of the *Medicaid Pharmacy Bulletin*, read them, and believed them to contain useful and reliable information. Moreover, the facts set forth in Paragraph 21 rebut assumptions made by the United States' expert witness on damages. As such, the *Medicaid Pharmacy Bulletin* is admissible under several Federal Rules of Evidence, including, but not limited to:

- Rule 801(d)(2)(B) (statement not hearsay if a "party has manifested an adoption or belief in its truth");
- Rule 801(d)(2)(D) (statement not hearsay if it is a "statement by the party's agent or servant concerning a matter within the scope of the agency or employment, made during the existence of the relationship");
- Rule 803(6) (hearsay exception for a "memorandum, report, record, or data compilation, in any form, of acts, events, conditions, opinions, or diagnoses, made . . . from information transmitted by, a person with knowledge")

- Rule 803(8) (hearsay exception for "[r]ecords, reports, statements, or data compilations, in any form, of public offices or agencies");

- Rule 803(18) (hearsay exception for "statements contained in published treatises, periodicals, or pamphlets on a subject of . . . medicine, or other science or art" when "called to the attention of an expert witness upon cross-examination"); and

- Rule 807 (residual hearsay exception for statements not covered by other rules, but with "equivalent circumstantial guarantees of trustworthiness")

Moreover, the hearsay rule does not apply where statements are relevant for purposes other than the truth of the matter asserted, including to show a party's knowledge, motivation, intent, or state-of-mind. *See, e.g.*, *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 614 F. Supp. 2d 90, 103 (D. Mass. 2009) (overruling hearsay objection to documents introduced in order "to show the Inventors' knowledge … in late 1998 and early 1999").

22. The United States admits to the substance of this paragraph. The additional facts added by the United States do not dispute the purpose of this paragraph, namely, that some state Medicaid programs utilized alternative reimbursement methodologies—different from EAC, U&C, MAC, or FUL—for compounded drugs.

23. The United States admits to the substance of this paragraph. The additional facts added by the United States do not dispute the import of this paragraph.

24. The United States admits to the substance of this paragraph. The additional facts added by the United States do not dispute the import of this paragraph.

25. The United States admits to the substance of this paragraph. The additional facts added by the United States do not dispute the import of this paragraph.

26. The United States admits to the substance of this paragraph, including that each of the Myers & Stafford reports listed in this Paragraph "reported increased dispensing costs associated with the provision of home infusion and I.V. solutions." Its purported "dispute" refers

to unstated "characterizations" and thus is irrelevant and does not require a response. The additional facts added by the United States do not dispute the import of this paragraph.

27. The United States admits to the substance of this paragraph. The additional facts added by the United States do not dispute the import of this paragraph.

The United States mischaracterizes the September 4, 1994 State Medicaid Agency Regional Bulletin, which merely reflects CMS's long-term policy of opposing dispensing fees that include or consist of a percentage markup from ingredient cost. *See* 40 Fed. Reg. 34516, 34516 (August 15, 1975) ("[a percentage markup] is not acceptable since a percentage mark-up would be an incentive to use higher cost drug items and thus it would run counter to the objectives of the regulations."); *see also Tex. Dep't of Human Servs.*, DAB 961 (H.H.S. Departmental App. Bd. June 9, 1988), *available at* 1988 WL 486063 (H.H.S.) ("There is no economic rationale for the fee to fluctuate according to the ingredient cost value of each prescription.") (citation omitted). Any suggestion that the federal regulations prohibited the practice of cross-subsidization is inconsistent with controlling HHS authority and the actual practice of the states. (Defs. Comb. Add'l SOF ¶¶ 24-26, 33-36, 44-57.)

35. The United States admits to the substance of this paragraph. Its purported "dispute" refers to unstated "characterizations" and thus is irrelevant and does not require a response.

37. The United States admits to the substance of this paragraph, despite its objection that the paragraph was "vague." The United States' boilerplate, unsubstantiated vagueness objection should be deemed waived and disregarded. *See United States v. Zannino*, 895 F.2d 1, 17 (1st Cir. 1990) ("issues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.'").

B. Medicare

40. The United States does not dispute the facts set forth in the paragraph. The United States' objection that the paragraph contains legal conclusions is immaterial. To the extent that the paragraph contains issues of law, they may be determined in connection with the Court's resolution of Abbott's summary judgment motion. It does not create a material dispute of fact precluding summary judgment.

41. The United States does not dispute the facts set forth in the paragraph. The United States' objection that the paragraph contains legal conclusions is immaterial. To the extent that the paragraph contains issues of law, they may be determined in connection with the Court's resolution of Abbott's summary judgment motion. It does not create a material dispute of fact precluding summary judgment.

42. The United States does not dispute the facts set forth in the paragraph. The United States' objection that the paragraph contains legal conclusions is immaterial. To the extent that the paragraph contains issues of law, they may be determined in connection with the Court's resolution of Abbott's summary judgment motion. It does not create a material dispute of fact precluding summary judgment. The additional facts stated by the United States do not dispute the facts contained in the paragraph. Abbott disputes that Mr. Stark closely observed Abbott's individual price reporting, as well as any effort to impute one Congressman's personal view to all of Congress.

44. The United States does not dispute the facts set forth in the paragraph. In response to the United States' statement that it "disputes any implication that the program memorandum implemented a policy to pay inflated amounts for drugs or that the memorandum sanctioned the reporting of false or fraudulent pricing to the compendia referenced in the

statement," Abbott notes that on May 31, 2000, HHS Secretary Donna Shalala made the following statement in a letter to Congressman Tom Bliley:

> Because the estimated acquisition cost approach has proved unworkable, in 1997, the President proposed legislation to pay physicians their actual acquisition costs. . . . Unfortunately, Congress did not adopt the Administration's proposal.
>
> Indeed the HHS Inspector General found payments based on average wholesale price data to be 11 to 900 percent greater than the prices available to the physician community. Therefore, in 1998, the President again proposed paying physicians their actual acquisition cost to 'ensure that doctors are reimbursed no more, and no less, than the price they themselves pay for the medicines they give Medicare patients."
>
> * * *
>
> Unfortunately, Congress did not adopt the Administration's proposal. Instead, the Balanced Budget Act reduced Medicare payment for covered drugs from 100 percent to 95 percent of average wholesale price. This recaptures only a fraction of the excessive Medicare payment amounts because, until recently, available average wholesale price data did not correlate to actual wholesale prices for certain Medicare-covered drugs.

(*See* Defs. Comb. Add'l SOF ¶ 115.).

46. The United States admits that the disputed document was in CMS's files and produced by CMS in this case. If the United States has evidence that its document was not drafted by Mr. Hash and/or was not distributed to Mr. Thrum, it should provide that evidence. The document indicates that it is from Mr. Nash and to Mr. Thrum. Because the United States withheld the document during discovery, Abbott was not permitted to ask relevant witnesses about its authorship, distribution, and, most importantly, content during discovery.

48. The United States' objection that the paragraph contains legal conclusions is immaterial. To the extent that the paragraph contains issues of law, they may be determined in connection with the Court's resolution of Abbott's summary judgment motion. It does not create

a material dispute of fact precluding summary judgment. Its purported "dispute" refers to unstated "mischaracteriz[ations]" and thus is irrelevant and does not require a response. Abbott notes that the GAO report cited by the United States also included the following recommendation: "Institute a process to monitor access to Medicare part B-covered drugs to ensure that payment changes do not negatively affect access for particular drugs, or groups of beneficiaries or in certain geographic areas." In its response to the GAO report, CMS stated:

> The GAO confirms the findings of its previous reports along with previous reports from the Office of Inspector General that Medicare's payments for drugs are substantially higher than the actual costs to physicians and other providers acquiring these drugs. Physicians and other providers indicate that while Medicare overpays for the cost of the drugs, Medicare payments sometimes do not adequately compensate for services related to furnishing the drugs. We agree with GAO that Medicare needs to pay appropriately for all Medicare benefits, including the drugs we currently cover, as well as, the services required to furnish these drugs. We look forward to working with the Congress and GAO to address this important issue.

When Congress enacted legislation to reduce Medicare's payment for drugs, it also increased payment for services associated with administering drugs.

49. The United States' objection that the paragraph contains legal conclusions is immaterial. It does not dispute the facts set forth in this paragraph. To the extent that the paragraph contains issues of law, they may be determined in connection with the Court's resolution of Abbott's summary judgment motion. It does not create a material dispute of fact precluding summary judgment. Abbott disputes the materiality of the United States' citation to *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004), which is irrelevant to whether Mr. Scully's testimony is relevant or admissible. The United States fails to set forth any formal legislative record regarding the Congressional intent in exempting infusion drugs administered through durable medical equipment from the new ASP methodology, much less any that is

inconsistent with Mr. Scully's testimony. Abbott disputes that Mr. Stark closely observed Abbott's individual price reporting, as well as any effort to impute one Congressman's personal view to all of Congress.

C. Federal Testimony

50. The United States does not dispute the facts set forth in the paragraph, which are that Dr. Vladeck, Ms. DeParle, and Mr. Scully provided the quoted testimony. The United States' vagueness objection is baseless. As the quoted excerpts make clear, the deposition questioning asked for the witnesses' understanding regarding how AWP was used in regulations and statutes. To the extent that DOJ believes its litigating position on the interpretation of AWP should be given greater weight than these CMS administrators, that position is disputed. Abbott disputes the materiality of the United States' citation to *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004), which is irrelevant to whether the quoted testimony is relevant or admissible. Abbott further states that the United States has consistently evaded providing sworn testimony from the agency on how it interpreted AWP in the relevant Medicare statutes and regulations. (Defs. Comb. Add'l SOF ¶ 105.)

51. *See* reply to paragraph 50, *supra*.

52. The United States does not dispute the facts set forth in the paragraph, which are that Dr. Vladeck provided the quoted testimony.

53. The United States admits to the substance of this paragraph. The remainder of the United States' response is unresponsive and immaterial. Abbott disputes the United States contention that the "spreads" referred to the article are "much smaller" than the spreads at issue in this case. The United States' claim that the quoted publication is "hearsay" should be disregarded, as the United States develops no argumentation in support of its theory. *See United States v. Zannino*, 895 F.2d 1, 17 (1st Cir. 1990) ("issues adverted to in a perfunctory manner,

unaccompanied by some effort at developed argumentation, are deemed waived.'"). In any event, the hearsay rule does not apply where statements are relevant for purposes other than the truth of the matter asserted, including to show a party's knowledge, motivation, intent, or state-of-mind. *See, e.g., Akamai Techs., Inc. v. Limelight Networks, Inc.*, 614 F. Supp. 2d 90, 103 (D. Mass. 2009) (overruling hearsay objection to documents introduced in order "to show the Inventors' knowledge … in late 1998 and early 1999.")

55. The United States admits to the substance of this paragraph. The United States' claim that the quoted publication is "hearsay" should be disregarded, as the United States develops no argumentation in support of its theory. *See United States v. Zannino*, 895 F.2d 1, 17 (1st Cir. 1990) ("issues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.'"). In any event, the hearsay rule does not apply where statements are relevant for purposes other than the truth of the matter asserted, including to show a party's knowledge, motivation, intent, or state-of-mind. *See, e.g., Akamai Techs., Inc. v. Limelight Networks, Inc.*, 614 F. Supp. 2d 90, 103 (D. Mass. 2009) (overruling hearsay objection to documents introduced in order "to show the Inventors' knowledge … in late 1998 and early 1999.")

57. Abbott concurs that Paul Chesser was employed by the Office of Inspector General, Office of Audit Services.

59. Abbott concurs that Ben Jackson is a former OIG employee. *See also* reply to paragraph 50, *supra*.

D. State Testimony

60. The United States does not dispute the facts in paragraph 60, which are that the witnesses provided the quoted testimony. The remainder of the United States' response is irrelevant to this paragraph and immaterial for purposes of Abbott's motion.

61. The United States does not dispute the facts in paragraph 61, which are that the witnesses provided the quoted testimony. Abbott disputes that it has selectively quoted from "a handful of Medicaid officials whose testimony supported Abbott's position." Abbott has responded to, or provided evidence related to, the United States' additional facts in other pleadings filed concurrently herewith. Based on the evidence cited in those other pleadings, the evidence overwhelmingly shows that state Medicaid officials understood that AWP prices reported in the compendia were not a reliable indicator of acquisition cost for generic drugs, which would include the Subject Drugs. (Defs. Comb. Add'l SOF ¶ 1.) In any event, the remainder of the United States' response is irrelevant to this paragraph and immaterial for purposes of Abbott's motion.

III. THE GOVERNMENT'S MOTIONS TO EXTEND THE SEAL

64 - 68. The United States admits to the substance of these paragraphs. The remainder of the United States' responses are unresponsive and immaterial. As set forth in Abbott's reply brief, the United States does not (and cannot) refute that, whether Abbott had informal notice or not, it had no ability to demand evidence from the United States or state Medicaid agencies through civil discover while the extended seal was in place. Abbott was thus prevented, by the seal, from gathering evidence from the Government for its defense.

Abbott denies in all respects that its actions with respect to a 2000 HHS-OIG subpoena "undermin[ed] the government's effort to conduct the investigation," but this fact is immaterial. As set forth in Abbott's summary judgment memorandum and reply brief, the United States abused the seal period and was not entitled to use it for one-sided discovery in building its litigation case against Abbott, including using its subpoena power to obtain one-sided document production.

The United States' further allegation that Abbott sought to discourage the United States from intervening in this matter, citing letters from 2000, is immaterial. Such a request, assuming it occurred, would not lead to the extension of the seal period; to the contrary, had the United States elected not to intervene, it could have either sought dismissal of the *qui tam*, at and the very least, the seal would have been lifted and the complaint served, thus setting in motion Abbott's right to engage in civil discovery. *See* 31 U.S.C. § 3730(b), (c).

70. The United States admits to the substance of this paragraph. The remainder of the United States' response is unresponsive and immaterial. As set forth in Abbott's reply brief, the United States does not (and cannot) refute that, whether Abbott had informal notice or not, it had no ability to demand evidence from the United States or state Medicaid agencies through civil discovery while the extended seal was in place. Abbott was thus prevented, by the seal, from gathering evidence from the Government for its defense.

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very least, the seal would have been lifted and the complaint served, thus setting in motion Abbott's right to engage in civil discovery. *See* 31 U.S.C. § 3730(b), (c).

72 - 78. The United States admits to the substance of these paragraphs. The remainder of the United States' responses are unresponsive and immaterial. As set forth in Abbott's reply brief, the United States does not (and cannot) refute that, whether Abbott had informal notice or not, it had no ability to demand evidence from the United States or state Medicaid agencies through civil discover while the extended seal was in place. Abbott was thus prevented, by the seal, from gathering evidence from the Government for its defense.

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IV. PROFFERED TESTIMONY OF MARK G. DUGGAN, PH.D.

79. The United States' response fails to explain how the cited references do not support the assertions in the paragraph; they do. Exhibit DR states: "Plaintiffs have engaged experts to explore alternative damages theories arising from NDC-based Medicaid

reimbursement for the Defendants' drugs identified in the Complaint and will supplement this part of its initial disclosures as necessary." Exhibit DS states: "The United States will rely on testifying experts to provide damage calculations." The paragraph should be deemed admitted.

84. While the United States contends that the "cited references to do not support Abbott's assertions in the first two sentences of the above statement," the United States does not dispute the statements in the first two sentences, or provide any explanation of why they are not correct. The paragraph should be deemed admitted.

85. In the testimony cited by Abbott, Duggan testified as follows:

> Q. I think the gist of the testimony there was that you were not advocating for a specific parameter to be used in the difference calculation; is that right?
>
> A. I think that that's -- yes.

(Ex. DU at 427:17-21.) The United States does not cite any support for the notion that Dr. Duggan has proffered an opinion on what percentile price should be used in his "difference" calculation.

86. Abbott does not dispute the United States' clarifying explanations to Table 1 of Dr. Duggan's report. The purpose of paragraph 86, which the United States does not dispute, is that Dr. Duggan computed average selling prices that were less than $2.00 for 37 of the 44 NDCs, and less than $1.00 for 29 of the 44 NDCs. Thus, the alleged "spreads" cited by the United States translate, collectively, to relatively small dollar amounts.

87. The United States' response to the third sentence—"Dr. Duggan's 'difference' calculation does rely upon claims data produced by Indiana Medicaid"—is misleading. The United States is apparently referring to the fact that the aggregate SMRF/MAX and SDUD that Duggan used in his Indiana "difference" calculation originally came from information provided by Indiana. The point of Abbott's paragraph 87 is that, unlike the ten states for which Dr.

Duggan performed a separate "difference" calculation based upon detailed claims data produced by the states for this litigation, the calculation for Indiana did not rely upon detailed claims data produced by the Indiana. Dr. Duggan's report and deposition admit this:

> Q. And it is for those twelve states that you use claims data that was produced by the state Medicaid program; is that right?
>
> MS. THOMAS: Objection.
>
> Q. Strike that. It is for those twelve states minus Indiana for which you use claims data provided by the Medicaid program?
>
> MS. THOMAS: Objection.
>
> A. Provided by the state Medicaid agencies or --
>
> Q. Yes.
>
> A. That is my -- yes. That is correct.
>
> Q. And how is it that you came to use the claims data provided by the states for those eleven states?
>
> * * *
>
> Q. And 11 of those states are ones where you use claims data produced by the state to perform the analysis; is that right?
>
> A. Right. And the discrepancy between the 11 and 12 is Indiana where I considered that data but discovered it to have problems. And that was one of the values of having data from three different sources. I can sort of check data sets against one another.

(*See* Ex. DU at 249:15-250:5.) Nothing in paragraphs 12 through 16 of Dr. Duggan's Declaration, which do not even mention this issue, is to the contrary. Rather, in paragraph 48 of his Declaration, Dr. Duggan states: "Again, the United States directed me to drop Ohio and I used a different approach for Indiana (with respect to my Abbott analysis) because my review of the data collected directly from the state showed it to be unreliable."

89. The United States admits the substance of this paragraph. The remainder of the United States' response does not contain material or undisputed facts, but expert opinion,

argument, and legal conclusion; therefore, not response is required. For the reasons set forth in its motion to exclude Dr. Duggan's extrapolations, Dkt. No. 6175, Abbott disputes the contention that "Dr. Duggan has demonstrated those states to be representative of the other states." Neither his report, deposition, or untimely Declaration do so.

91. The United States offers no evidentiary basis to dispute the statement that "Dr. Duggan did not document what sampling methodology, if any, that he employed in extrapolating his 'difference' calculations from one set of states to another set of states." The point of Abbott's paragraph 91 is that Dr. Duggan did not document what *sampling* methodology he used in his extrapolation—*e.g.*, why he choose some states over others—not whether his overall "difference" analysis was documented. Paragraph 91 should therefore be deemed admitted.

93. The United States' response is misleading. The United States is apparently referring to the fact that the aggregate SMRF/MAX and SDUD that Duggan used in his calculations for states beyond Illinois, Florida, California, New Jersey, New York, Kentucky, Missouri, Michigan, Louisiana, and Wisconsin originally came from information provided by the states. The point of Abbott's paragraph 93 is that, unlike the ten states for which Dr. Duggan performed a separate "difference" calculation based upon detailed claims data produced by the states for this litigation, the calculation for the other states did not rely upon detailed claims data produced by the states. There is no dispute about this.

105. The United States provides no factual basis to dispute the facts stated in paragraph 105. Therefore it should be deemed admitted. Nor does the United States provide any factual basis for its suggestion that, "[t]o the extent that drugs such as dextrose, sodium chloride or Vancomycin were included on an IDC list, the IDC prices could have been lower, higher or the same as what the prices would have had it used the EAC methodology." The documents

produced by the state of Maryland demonstrate that Maryland's IDC prices were much lower than EAC for Abbott's dextrose, sodium chloride, and vancomycin. (*See, e.g.*, Ex. 1 (MD0005758) (sodium chloride), Ex. 2 (MD0020892 (dextrose).)

107. The United States provides no factual basis to dispute the first sentence. Therefore it should be deemed admitted. The document cited by Abbott shows that Maryland had an IDC in place for vancomycin starting in September 1996. (Ex. EK at MD0021496.) The testimony cited by the Government, related to dextrose (not vancomycin) is immaterial to this paragraph and should be disregarded.

112. The United States provides no factual basis to dispute paragraph 112. With respect to the first sentence, the United States fails to explain why Abbott's statement is incorrect; Abbott's statement was not intended to encapsulate everything that Dr. Duggan did with SMRF/MAX data but, rather, to summarize an analysis he did that is discussed in footnote 45 of his initial report. The first sentence should be deemed admitted. The United States fails to explain why the second sentence is incorrect. Dr. Duggan explained that the analysis he performed that is discussed in footnote 45 of this report was done in order to look at the issue of "selection bias." (Ex. DU at 498:8.) The second sentence should be deemed admitted. The point of the rest of paragraph 112 is that Dr. Duggan performed his "selection bias" test, described in footnote 45 while Ohio—a state with aggressive MACs (and, thus, a smaller "difference")—was still in the mix. He did not update that analysis after Ohio was removed from this analysis.

114. The United States provides no factual basis to the first sentence of paragraph 114, that "Dr. Duggan did not analyze whether the number of units per claim is consistent across the states." The United States provides no evidence that Dr. Duggan did conduct such an analysis.

Therefore it should be deemed admitted. In the testimony cited by Abbott, Dr. Duggan admitted that he did not use "units amount" field in SDU data. (Ex. DU at 690-91.)

115. The United States provides no factual basis to dispute paragraph 115. The United States fails to explain what other analyses Dr. Duggan did to assess the comparability of the eleven states to the 38 extrapolated states; nor does Dr. Duggan's Declaration describe any additional analyses. The paragraph should therefore be deemed admitted.

116. The United States admits to the substance of this paragraph. Its purported "dispute" refers to unstated "characterizations" and thus is irrelevant and does not require a response.

117. The United States provides no factual basis to dispute paragraph 117. It does not dispute that the Part B carriers from which extrapolated were not chosen at random, and that Dr. Duggan did not document any sampling methodology. Therefore the first two sentences of the paragraph should be deemed admitted. Nor does the United States dispute that it has, in fact, asserted privilege over communications with DOJ and carrier representatives relating to the collection of Medicare pricing data.

120. The United States provides no factual basis to dispute any of the sentences of paragraph 120. Its purported "dispute" refers to unstated "characterizations" and thus is irrelevant and does not require a response. Therefore the paragraph should be deemed admitted.

121. The United States provides no factual basis to dispute any of the sentences of paragraph 121. It provides no factual basis to dispute the contention that Dr. Duggan did not analyze whether, on each of the claims upon which he computes a "difference," the claim was paid based upon any price reported in the compendia; nor does Dr. Duggan's Declaration provide any evidence to the contrary. Dr. Duggan testified:

> Q. How about, do you do an analysis that tries to trace if the claims were paid under the AWP or WAC formula?
>
> A. I guess I'm unclear on what you mean.
>
> Q. Let me ask it a different way.
>
> A. Okay.
>
> Q. Have you done an analysis where you can say for all of these 500,000 claims, roughly, in Illinois, I have gone through and I can tell you that they all are reimbursed at charges, under an AWP minus formula consistent with the state plan, or a MAC?
>
> MR. LAVINE: Object to form.
>
> THE WITNESS: I'm not sure if I did that specifically for the State of Illinois. But as I -- so I'm not sure if I did that for Illinois. I don't recall doing that for Illinois.
>
> BY MR. TORBORG:
>
> Q. Okay. I have your log of what you did and I don't see that there. I'm just making sure I'm not missing something.
>
> A. Sure.

(Ex. DU at 762:7-763:6.) Dr. Duggan's working papers do not contain any evidence that he analyzed whether each of the claims at issue was paid based upon any price reported in the compendia.

122. The United States provides no factual basis to dispute any of the sentences of paragraph 122. Its purported "dispute" as to the first sentence refers to unstated "characterizations" and thus is irrelevant and does not require a response. The sentence should therefore be deemed admitted. Nor does the United States provide any explanation of why the second sentence—"Dr. Duggan did not ask Myers & Stauffer to determine which states established MAC pricing for the 44 Complaint NDCs"—is, as the United States contends, "patently inconsistent with Dr. Duggan's testimony." In the testimony cited by Abbott, Dr. Duggan stated, when asked if he asked Myers & Stauffer to determine whether states had MACs

on the 44 Complaint NDC: "No. That is the -- that's precisely the kind of thing that I strove to do in my analysis of the data, and -- but they -- *I did not ask them to catalogue what time periods and what -- you know, what NDC quarter combinations might there have been a MAC in effect*." (Ex. DU at 751:6-11) (emphasis added). There is no evidence that either Dr. Duggan or any of his consultants analyzed which Medicaid programs established MAC pricing for the 44 Complaint NDCs, when, and at what levels. This sentence should therefore be deemed admitted.

123. The United States provides no factual basis to dispute paragraph 123. The United States has not provided any evidence of anything that Dr. Duggan did to analyze what impact, if any, that AWPs, WACs, or DPs reported in the compendia had on state MAC pricing; nor does Dr. Duggan's Declaration. Paragraph 123 should therefore be admitted. In the testimony cited by Abbott, Dr. Duggan stated that "[t]he determination of MAC prices is not something that I exhaustively studied in this . . . ," and he agreed that he was "not familiar with in each instance with the process that states used to establish those MACs." (Ex. DU at 791:5-8; 794:11-16.)

124. The United States provides no factual basis to dispute paragraph 124. The United States has not provided any evidence to dispute the indisputable fact that Dr. Duggan's "difference" calculation includes claims that were, in fact, paid on the basis of a MAC. Dr. Duggan clearly testified that his "difference" includes such claims:

> Q. Now, for situations where there was a MAC on one of the 44 NDCs in a particular quarter, the amount that was paid by the Medicaid program is not based on the reported price of the Abbott product.
>
> MR. LAVINE: Object to form.
>
> THE WITNESS: That's an input in it, but if ultimately what -- if the MAC results in a lower amount paid than would result if the AWP were used, then the AWP isn't used -- it is used, right, it's used in the adjudication formula, but it is, it's not the one on which the ultimate payment amount is based.

BY MR. TORBORG:

Q. And there are instances where you're still calculating a difference, right? In those instances, right?

A. That is correct. And in some cases, it may be zero.

(Ex. DU at 765:18-766:15.)

127. The United States provides no factual basis to dispute paragraph 127. If the United States believes Abbott's description of Dr. Duggan's approach is incorrect, it should explain why. Paragraph 127 should therefore be admitted.

128. The point of paragraph 128 is that, for none of the ten states, did Dr. Duggan utilize detailed claims data produced by the states for this litigation to compute his difference for the entire time period of his analysis. There is no dispute on that.

130. The United States provides no factual basis to dispute paragraph 130, namely, that Dr. Duggan's working papers show a general decline across the states in the percentage of claims reimbursed on the basis of provider charges. Paragraph 130 should therefore be admitted. The United States' statement regarding the purported impact of "enforcement efforts of the United States" is unsupported and immaterial to this paragraph.

133. Abbott notes that the SMRF/MAX data, while showing some information at the claims level, does not show the basis of payment or separate out dispensing fees from ingredient cost payments. *See* paragraph 135.

135. The United States provides no factual basis to support its contention that "SDUD or SMRF/MAX data together with other sources of information could be used to determine if a claim was paid using a state MAC." Regardless, Dr. Duggan did not perform such an analysis. *See* paragraph 122.

140. Paragraph 140 was meant to refer to "Utah Medicaid," not "Pennsylvania Utah Medicaid." There was a typographical error in paragraph 140 regarding the "DIFF-FRAC" (which, corrected, is .577262 (57.7262%)), but that did not effect the computation contained in Abbott's motion to exclude Dr. Duggan's opinion, which reflected the correct "DIFF-FRAC" and demonstrated the absurdity of his extrapolations for Utah. The remainder of the United States' response is immaterial to this paragraph.

157. To the extent that Dr. Duggan purports to testify on the subject of damages, or the extent to which states overpaid for the Subject Drugs, he should have done more than simply review the reimbursement formulas utilized by state Medicaid programs to ascertain their policies in the area of drug reimbursement. He should have reviewed the factual record that was available to him on these issues, rather than simply performing a mathematical computation.

158. *See* reply to paragraph 157, *supra*.

159. *See* reply to paragraph 157, *supra*.

160. *See* reply to paragraph 157, *supra*.

161. *See* reply to paragraph 157, *supra*.

162. *See* reply to paragraph 157, *supra*.

163. *See* reply to paragraph 157, *supra*.

164. *See* reply to paragraph 157, *supra*.

165. *See* reply to paragraph 157, *supra*.

166. *See* reply to paragraph 157, *supra*.

V. OTHER

169. The United States admits to the substance of this paragraph. The United States' response fails to explain what else in interrogatory response should be reviewed for the purposes of this paragraph. It does not cite to any "context" from the rest of the interrogatory which

changes the nature of the admitted-to response. To the extent that the United States' statement is viewed as an objection, it should be overruled.

170. The United States admits to the substance of this paragraph. Abbott disputes any implication that the United States has ever produced a representative sample of the allegedly false *claims* (what was submitted to the Medicare and Medicaid programs by providers) at issue. With respect to the claims *data*, Abbott disputes that it is a representative sample because it does not include "the population [of] the whole class of units that are of interest"—here, the universe of allegedly false claims from all states and contractors—such that any given claim had a "known, nonzero probability of being chosen." *See* David H. Kaye & David A. Freedman, *Reference Guide to Statistics*, in *Reference Manual on Scientific Evidence* at 90, 100 (Fed. Judicial Ctr. 2d ed. 2000).

The United States' claim that Abbott never "challenged whether the United States' sample was sufficient or compliant," is false. In both its briefing and at the hearing Abbott made clear what was required: "the sample of Medicaid claims include an allegedly 'false claim' for each NDC at issue, each year, and each state Medicaid program, and that the sample of Medicare claims include an allegedly 'false claim' for each J-Code at issue, each year, and each Medicare Carrier." (Dkt. No. 5173 at 7); *see also* Dec. 4, 2008 Hrg. Tr. at 50:16-19 ("[A]ll we're asking for is let's say program by program one a year for each of the drugs, for each of the NDCs at issue, each of the J-codes at issue on the sides. Give us a sample . . . .").)

171. *See* reply to paragraph 170, *supra*.

173. The United States provides no evidence to dispute Abbott's contention that, "[f]or portions of this time period, four states defined EAC exclusively in terms of WAC—Alabama, Florida, Massachusetts, and Rhode Island." That sentence should therefore be deemed admitted.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David S. Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 28th day of August, 2009.

/s David S. Torborg
David S. Torborg